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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,091	01/14/2002	Raymond P. Johnston	54404US008	6682

32692 7590 08/25/2004

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EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,091

Applicant(s)

JOHNSTON ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003 and 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-39 and 42-60 is/are rejected.
- 7) ☐ Claim(s) 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action

DETAILED ACTION

Response to Amendment

1. The appeal brief filed on 7/12/04 has been received. In light of applicants' arguments prosecution on this application is being reopened.
2. Claims 36-60 are pending in the instant application.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 36-37, 43, 45-47, 49, 51-54 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,632,731 ("Patel").

As regards claim 36, Patel discloses a medical treatment article comprising at least one fluid control film (12) as defined in the specification, comprising at least one microstructure bearing surface with a plurality of channels (perforations 13) therein that permit transport of fluid between medical treatment site (user) and a remote area (16, 17, 18). Note Fig. 1, col. 2, lines 20-29 and col. 3, lines 64-66.

As regards claim 37, Patel discloses the article as a wound dressing (title).

As regards claim 38, chamber (16) reads on applicant's reservoir.

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As regards claim 43, Patel discloses a polyolefin film (col. 3, lines 66-col. 4, lines 2).

As regards claim 45, channels (perforations 13) come are in contact with adhesive (22).

As regards claim 46, the wound dressing of Patel is a combination wound dressing and wound drain, and it is capable of being inserted into the medical treatment site.

As regards claim 47, the applicant should first note that it has been held that a recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

In further regard to claim 47, the fluid control film of Patel is capable of supplying a medicament from the fluid reservoir to the medical treatment site.

As regards claim 49, the applicant is reminded that it has been held that a recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. As such, at least of portion of the fluid control film (12) of Patel is **capable** of visual observation.

As regards claim 51, Patel inherently discloses the claimed method of using a medical article comprising at least one fluid control film component having at least one microstructure-bearing surface with a plurality of channels therein that permit transport of fluid between a medical treatment site and a remote area, the method comprising:

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placing the medical article in proximity to a medical treatment site so that the fluid control film component is capable of providing fluid communication between the medical treatment site and the remote area; and allowing the medical treatment article to transport fluid between the medical treatment site and the remote area (Figs. 1-3, col. 2, lines 20-29 and col. 3, lines 64-66). This method is accomplished by mere usage of the wound dressing of Patel.

As regards claim 52, fluid is transported from the medical treatment site to the remote area (16, 17 and 18).

As regards claim 53, chamber (16) reads on applicant's claimed reservoir.

As regards claim 54, note absorbent layers (17, 18).

As regards claim 58, Patel teaches transportation of the fluid from the medical treatment site to the remote area. However, it is inherent that when the absorbent material becomes saturated fluid flow will occur in the opposite direction, from the remote area to the medical treatment site.

5. Claims 51 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. U.S. 4,379,454 ("Campbell et al.").

As regards claim 51, Campbell et al. inherently disclose the claimed method of using a medical article comprising at least one fluid control film component (15) having at least one microstructure-bearing surface with a plurality of channels (micropores) (col. 5, lines 15-20) therein that permit transport of fluid between a medical treatment site (user) and a remote area (35), the method comprising: placing the medical article in

proximity to a medical treatment site so that the fluid control film component is capable of providing fluid communication between the medical treatment site and the remote area; and allowing the medical treatment article to transport fluid between the medical treatment site and the remote area. This method is accomplished by mere usage of the wound dressing of Patel.

Regarding claim 55, the fluid is transported from the remote area (35) to the medical treatment site (user).

Regarding claim 56, the fluid comprises a medicament (estradiol).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 39, 42, 44, 50, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel.

As regards claim 39, Patel fails to teach the claimed cross-sections of the channels. Absent a critical teaching and/or a showing of unexpected results derived from providing film with the claimed cross-sectional shapes, the examiner contends that the cross-sectional shape of the channels is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 42, Patel fails to teach the depth of the perforations, thereby failing to teach the perforations are between about 5 and 3000 microns deep. Absent a critical teaching and/or a showing of unexpected results derived from providing the channels that are between about 5 and 3000 microns deep, the examiner contends that deepness of the channels are an obvious design choice depending upon the intended use of the invention, and therefore not a patentably distinct feature.

As regards claim 44, Patel discloses the use of polyesters, polyolefins and the like polymeric materials for the film layer. Patel fails to specifically teach the materials as presently recited in claim 44. However, it has been held that the selection of a known material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1060). Therefore, it would have been obvious to one having ordinary skill in the art to modify Patel by constructing the film layer from one of the claimed materials depending upon the intended use. Additionally, the applicant should note that the presently claimed materials are polymeric materials similar to those disclosed by Patel, and one having ordinary skill in the art would have found it within the level of

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ordinary skill in the art to substitute a similar material for polyesters and polyolefins as an obvious design choice.

As regards claim 50, Patel is silent as to the translucency of the fluid control film. However, it would have been within the level of ordinary skill in the art to modify film layer (12) of Patel by substituting it for a film layer that is at least translucent in order to view a portion of the medical treatment site.

As regards claims 59 and 60, Patel fails to teach visually observing the medical treatment site by visually observing the medical treatment site through the transparent portion of the medical treatment article. However, it would have been within the level of ordinary skill in the art to modify film layer (12) of Patel by substituting it for a film layer that transparent in order to view a portion of the medical treatment site so as to insure the correct site is receiving the medicament.

9. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al.

As regards claim 57, Campbell et al. fail to disclose one of the claimed medicaments. However, it would have been *prima facie* obvious to one having ordinary skill in the art to modify Campbell et al. by substituting the disclosed medicament for any other type of medicament, such as those presently claimed.

Allowable Subject Matter

10. Claims 40 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments with respect to claims 36-60 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Kim M. Lewis
Primary Examiner
Art Unit 3743

kml

August 24, 2004